

Running head: HEMOSTATIC AGENTS

Leading Community Risk Reduction

Reducing the Risk of Uncontrollable Hemorrhage

Through the Use of Hemostatic Agents

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Certification Statement

I hereby certify that this paper constitutes my own product, that where the language of others is set forth, quotation marks so indicate, and that appropriate credit is given where I have used the language, ideas, expressions, or writings of another.

Signed: \_\_\_\_\_

### Abstract

The problem is that patients in the Central Jackson County Fire Protection District suffer traumatic wounds that result in uncontrollable hemorrhage. The descriptive research method was used to examine existing hemostatic agents to improve hemorrhage control and consider alternatives to the current methods used. The participant conducted a literature search, examined multiple hemostatic agents, interviewed and worked with researchers and inventors of hemostatic agents, and sought alternative solutions to the current methods of hemorrhage control. Statistics and case studies were cited retrospectively and concurrently to illustrate the use and efficacy of different agents. The research questions asked what current methods were in place for hemorrhage control, what methods or materials were needed to reduce patient risk, what alternatives existed, and what the implications were for the community in reducing uncontrollable hemorrhage. The hemostatic agent QuikClot® was determined to be the most effective and efficient hemostatic adjunct for the Fire District and its citizens.

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## Introduction

Death secondary to traumatic injuries in the United States is attributed to uncontrollable and exsanguinating hemorrhage in citizens 5-45 years of age, second only to HIV (Coats, et al., 2005). Emergency Medical Services (EMS) is one of the first stages of the healthcare system that people encounter in this country and the EMS workers have the potential to impact patient outcome through the care and treatment they provide. The Central Jackson County Fire Protection District (CJCFFPD) provides EMS to the citizens in Eastern Jackson County, Missouri, in and around the City of Blue Springs. The service area includes a seven to eight mile section of interstate highway, multiple state highways, industry, recreation, residential areas, and rural areas over a largely suburban district of 57 square miles. In the last four years, the Fire-based EMS system responded to over 4,000 requests for service each year that required ambulance transportation, almost one fourth of those involving trauma or potential traumatic injuries. Over a dozen patients per year died as a result of traumatic injuries in the District and at least two per year may have benefited from a hemostatic agent or adjunct during that time (P. Lininger, personal communication, November, 2005).

The research problem is that patients in the Central Jackson County Fire Protection District suffer traumatic wounds that result in uncontrollable hemorrhage. Uncontrollable hemorrhage leads to death. The purpose of this research was to examine new and emerging methods of controlling massive hemorrhage, secondary to trauma, to

reduce the risk of irreversible shock and death to patients treated by CJCFPD personnel.

The research method chosen for this applied research project was descriptive.

The research questions that will be answered in this paper are:

1. What methods are currently used by CJCFPD personnel to control massive hemorrhage secondary to trauma?
2. Why are other methods of hemorrhage control needed to reduce patient risk?
3. What methods outside of CJCFPD exist for control of massive hemorrhage?
4. What are the obstacles to obtaining and using methods of hemorrhage control not currently available to CJCFPD personnel?
5. What is the impact to the community of reducing the risk of uncontrollable hemorrhage?

### Background and Significance

Trauma is the number one cause of death in persons under the age of 44 and the fourth-leading cause of death of all ages (American Trauma Society, 2005). In the United States, trauma is the leading cause of lost workplace productivity and costs the nation in excess of \$180 billion per year in emergency room visits, hospitalization, surgery, and death (Society of Trauma Nurses, 2005). Missouri meets or exceeds the national rate of deaths due to trauma in every measurable category, according to the Centers for Disease Control (Centers for Disease Control and Prevention, 2001). The healthcare community, including EMS, is strongly committed to eradicating preventable injuries and death (American Trauma Society Injury Prevention Section, 2005).

Although a large number of deaths in the CJCFPD service area are not directly attributable to uncontrollable hemorrhage, citizens actually die each year from this malady (P. Lininger, personal communication, November, 2005). If these deaths are preventable and the care and treatment provided by EMS can be refined to reduce the incidence of morbidity and mortality, there is a professional, ethical obligation to make reasonable changes to reduce the incidence of death due to trauma. Multiple prevention programs already exist within the District to reduce the incidence of trauma. Adopt-A-School programs, education programs at public gatherings, focused school presentations, community interest group presentations, Youth Fire Starter counseling, seat belt programs, and printed materials are part of the effort by CJCFPD to reduce trauma in the community. In spite of prevention efforts, trauma still occurs (Westermann, 2005).

Trauma care is continually in a state of flux. The Midwest Trauma Society is a local organization that holds monthly meetings and an annual conference. Their mission statement reads: “The Midwest Trauma Society is formed for the purpose of promoting high standards of care for trauma victims; to create public and professional awareness of trauma; to sponsor and carry out educational programs for trauma professionals and others; to provide a forum for trauma professional and others; to exchange information and ideas and to support efforts of public education and prevention strategies of trauma as a health care issue” (Midwest Trauma Society, 2005). It is obvious that this mission statement is focused on promoting and advancing trauma care. CJCFPD is an active member of the Trauma Society and shares the vision of improved trauma care for the citizens and guests in their service area.

Although somewhat speculative, the author surmises that some of the earliest trauma cases involved dinosaurs attacking humans (Stevens, 2001) and cavemen attacking others with clubs (Kime, 2005). Trauma care is undocumented during those times and speculative; however, human nature would dictate that trauma was treated in some form to alleviate pain by the inflicted individual. Trauma care is first documented around the time of the Civil War and one of the first female physicians to work on the battlefield was awarded the Congressional Medal of Honor for her efforts (“Trauma care,” 2001). It is prudent to say that trauma care has been an issue of some degree since God created human beings (Holy Bible NIV, 1984 ).

Efforts to solve the problem of uncontrollable hemorrhage are also speculative up to the point of documentation by the Chinese, who used herbs, plants, and poultices to stop blood loss in ancient combatants (“Injury management,” 2005). In the Civil War, the treatment of choice was amputation, packing, and cauterization when the bleeding would not stop (Oliverio, 2004). Dr. Letterman developed ambulance evacuation systems in the Civil War to help get those who were bleeding to definitive treatment more quickly (Minken, 2004) and today’s EMS systems still use ambulance evacuation to get trauma patients to definitive care sites.

In 2003, the CJCFFPD Fleet Manager was moving some brake drums for a ladder truck on a hand cart. One of the brake drums begin to slide and the Fleet Manager grabbed it, cutting his palmar surface of his left hand and lacerating tendons, an artery, and a nerve. He applied direct pressure, called 911, and initiated an EMS response from CJCFFPD. Company 3, the Duty Chief, and an off-duty Chief Officer in the area of the



maintenance center responded. With direct pressure, a blood pressure cuff superior to the wound, added dressings, and pressure dressings, the wound continued to bleed through the bandages and pool in the floor of the ambulance. The patient exhibited and increased heart rate, a decreased blood pressure, pale and clammy skin, dizziness, and other signs and symptoms of moderate shock. Oxygen was applied by non-rebreather mask at 15 liters per minute, a cardiac monitor was applied, an IV of Lactated Ringers was initiated with a 16 gauge catheter, and the patient was rapidly transported to a Level II Trauma Center (Helverson, 2003). During call review by Chief Officers and medical personnel involved in the call, it was determined that a hemostatic adjunct may have helped prevent the progression of shock in this patient.

This problem has impacted patient care in the past, impacts it presently, and may have an impact in the future. However, addition of a hemostatic adjunct to the trauma protocol will provide an additional means of treating uncontrollable hemorrhage. Trauma is not declining in the CJCYPD service area (Westermann, 2005) and is the leading cause of death among people under the age of 44 in our country (American Trauma Society, 2005). It is the author's belief that a hemostatic adjunct is warranted in the CJCYPD EMS system.

These concerns were directly related to more than one of the five United States Fire Administration (USFA) operational objectives: reducing the loss of life in all age groups, reducing the loss of life in firefighters, risk-reduction, and a timely, appropriate response to emerging issues. Three of the five objectives address life safety; controlling hemorrhage is extremely important for life safety. If uncontrollable hemorrhage is the major cause of traumatic death and trauma is a leading killer in our country, the use of

hemostatic adjuncts to control hemorrhage becomes very important in resuscitation attempts and patient care. If a patient is bleeding and the hemorrhage is uncontrollable, the consequences can be deadly. Adding a means of controlling hemorrhage reduces the risk of traumatic death to those served by CJC/FPD.

Until 2004, CJC/FPD EMS personnel used the following means to control hemorrhage in trauma patients: direct pressure, gauze dressings, impermeable dressings, pressure point applications, constricting bands, and as a last resort, tourniquets (Block, et al., 2004). In 2004, the hemostatic agent QuikClot® was introduced on a trial basis and continues to be evaluated today.

The research performed in completing this paper examined what standards exist, what incidence of “death by trauma exist” in the service area, and what options exist to improve current practice with hemostatic adjuncts. Other services, researchers, field environments, combat zones, and foreign countries were visited and practices observed to find possible solutions to the problems that exist with uncontrollable hemorrhage and hemostatic agents.

The author conducted this research with a focus on the descriptive method. He does not profess to be an expert in the field of trauma care and hemostatic agents; however, his desire to produce an accurate assessment of current practices and examine options for improvement is the main purpose of this research.

## Literature Review

The current means of controlling hemorrhage in trauma patients is not meeting the needs of the Central Jackson County Fire Protection District in light of continually changing technology and developments in the field of trauma care and hemostatic agents (Perciballi, 2004). War and combat produce advances in trauma care (Mishky, 2004). Improvements appear readily available in the treatment of uncontrollable hemorrhage in trauma patients that is applicable for the civilian EMS sector after developing and testing in the combat environment (Gullong, 2002). One major obstacle in improving the current treatment capabilities in the military appears to be political and stems from different groups of researchers developing different classes of hemostatic agents (Butler, 2003 & Holcomb, 2002). These political issues do not appear to be a factor in the civilian sector unless they result in a specific product being discontinued because the military medical community does not support it.

In 1993, nineteen U.S. military personnel were killed in Somalia during a “snatch and grab” operation to apprehend a warlord. All of them died from trauma of combat and all but one of those were attributed to uncontrolled hemorrhage (Bowden, 1999). The search for better bleeding control and easily fielded hemostatic agents accelerated during the “after action” sessions that ensued (Butler, 1999). An overview of current hemostatic agents follows:

Hemostatic agents to promote clotting -

Aminocaproic acid – enhances clotting by slowing or stopping fibrinolysis (breakdown of blood clots).

Tranexamic acid – same mechanism as aminocaproic acid.

Aprotinin – a naturally occurring agent isolated from bovine lung tissue that

that reduces bleeding during and after surgery. The mechanism is thought to involve effects on platelet function as well as coagulation and fibrinolysis.

Desmopressin – a synthetic version of naturally occurring hormone, causing a dose dependent increase in plasma factor VIII, plasminogen activator, and factor VIII related antigen and ristocetin cofactor activities.

Topical Hemostatic Agents – pads, powders, pastes, sponges, solutions, meshes, and special dressings that may be used to control blood loss from open wounds by promoting the clotting of whole blood or plasma.

Tissue adhesives – fibrin glue is human-derived tissue adhesive that may be used for hemostasis and sealing of tissues. It may be manufactured from clotting factors taken from donor plasma (fibrinogen and thrombin) or made intraoperatively out of fibrinogen taken from the patient's own blood.

Vitamin K – a synthetic product similar to naturally occurring Vitamin K. It assists and is required for the production of certain blood clotting factors.

Recombinant Antihemophilic Factors –

Recombinant Factor VIIa – prevents or controls bleeding. Used in patients with hemophilia, thrombocytopenia, and severe multiple factor deficiencies.

Recombinant Factor VIII – essential for clotting and the maintenance of effective hemostasis, mostly effective in Hemophilia A.

Recombinant Factor IX – temporarily replaces patients deficient in factor IX with Hemophilia B. (“Hemostatic agents,” 2006).

Bart Gullong of Z-Medica is one of the primary founders of the product QuikClot®, a hemostatic agent that resembles granular, clumping sand. It consists of

Zeolite, a volcanic mineral that absorbs moisture quickly through an exothermic reaction, concentrating platelets and promoting almost immediate clotting (Gullong, 2002).

QuikClot® recently became available in a sponge that was made by placing the granules in a mesh bag, more commonly referred to as a “teabag” by trauma surgeons (QuikClot ACS, 2005 & Funk, 2005). Alam, et al. (2004) conducted a study in 2003 comparing Zeolite with other hemostatic agents and found it to be the only adjunct to provide a zero percent mortality rate in swine models. A paper presented in 2005 cited uses in Operation Iraqi Freedom and Operation Enduring Freedom, highlighting the fact that lives were saved with QuikClot® (Rhee, 2005). Arnaud, et al., 2004, presented a poster through the Naval Medical Research Center showing the efficacy of QuikClot® in both forms, granular and the Advanced Clotting Sponge® or teabag. Since its inception in the mid-90’s, QuikClot® is carried by every Marine in a combat zone, by Navy Seals, and many U.S. Army soldiers (Eisman, 2004). It became available to the civilian sector in 2002 and some of the first EMS and law enforcement systems to put it in the field were in Florida, with documented uses and successes (Moody, 2004). QuikClot® costs roughly ten dollars per pack in the government supply system and twenty dollars per pack in the civilian market (U.S. Cavalry, 2005).

Another hemostatic adjunct that has received significant attention and is fielded by the U.S. Army and various special operations organizations is the HemCon® dressing, or chitosan sponge. This dressing is a four inch by four inch sponge made of shrimp shells and vinegar, produced by Hemorrhage Control Technologies of Portland, Oregon (Cardenas, 2003). The use of the HemCon® dressing is becoming more widespread throughout the U.S. military (Holcomb, 2005) and is not yet available in the civilian

market. The cost to the government is roughly \$100 per sponge. The attention that this adjunct has received is not without controversy. It appears that the chitosan dressing was backed by the U.S. Army Institute of Medical Research after the thrombin dressing that they fielded was pulled from the market in 2002-2003 (Butler, 2002). The thrombin dressing was tested and fielded with special operations troops around 1999-2000 but crumbled when carried for any length of time in a field environment (Holcomb, et al., 2005). When recalled, the Army Institute of Medical Research had to look for another hemostatic agent to work on that was durable enough to withstand a field environment. The chitosan dressing met that need over the zeolite granules because it more closely resembled the Institute's project and view on hemostatic adjuncts. This dressing has found a few supporters among medical professionals in the special operations community and the Committee on Tactical Combat Casualty Care at U.S. Special Operations Command issued a statement that reads: "... because of its safety and ease of application, the HemCon® dressing represents the best current option for external hemostasis on the battlefield in casualties whose bleeding sites are not amenable to the use of a tourniquet." Holcomb, et al. (2005) published an article in the U.S. Army Medical Department Journal in Spring 2005 on the chitosan-based hemostatic dressing and experience in combat operations, citing a 95% effectiveness with the dressing. A swine study was conducted to mirror the zeolite swine study by Dr. Alam, showing a decrease in mortality but suggested further studies were needed (Cardenas, 2003).

A third hemostatic adjunct that was reviewed was Novo Seven, or recombinant factor VIIa. This is a component that naturally occurs in the human body and is an integral part of the clotting cascade system. As a hemostatic agent, this material is

produced by isolating the human gene on chromosome thirteen for factor VIIa, then transfecting the gene into a hamster kidney to produce Novo Seven. This takes the chance of viral contamination out of the equation and makes the adjunct much safer than production with human plasma products (“Novo Seven,” 2005). Although the cost is reported to be \$0.81 per microgram, the recommended dose is 90 micrograms per kilogram of patient weight, or roughly \$900 per dose, repeated every two hours until hemostasis is achieved (“Novo Seven,” 2005). It is unknown if this cost includes developmental costs and retail pricing. The Israeli Army and Australian Defense Forces have tested Novo Seven with military patients. They report that while they have excellent results in initial test cases, the average cost per patient is \$3,400 for the agent (Kossman, et al., 2004 and M. Carr, personal communication, 2004).

The author was fortunate to deploy in a combat environment with the U.S. Army in 2004 and 2005 with Dr. Marcus Carr, a primary researcher on the Novo Seven development project. Dr. Carr stated his opinion that Novo Seven was an excellent hemostatic agent, very expensive, and needed more clinical trials and use before it became a widespread adjunct, particularly in the “out of hospital” environment (M. Carr, personal communication, 2004). He discussed QuikClot® and HemCon®, in depth, as hemostatic adjuncts and stated that in his opinion, each had their own place and situations for use in the field. As an Internist and a Hematologist, he is considered a subject matter expert and was a wealth of information on clinical matters relating to clotting system malfunctions.

CJCFPD personnel currently use methods taught in the national paramedic curriculum to control hemorrhage (Frame, et al., 2003). In addition, QuikClot® was

placed on the ambulances last year for use on a trial basis. Current national curricula state that external hemorrhage secondary to trauma is controlled with direct pressure, pressure bandages, elevation of the limb, and pressure points medial to the wound site (Bledsoe, et al., 2001). Current department protocol dictates use of these methods with the addition of QuikClot® as an adjunct (Block, et al., 2004). In addition, an Israeli Trauma Dressing was acquired for testing this year and is marketed under the name of “The Emergency Bandage” by Performance Systems Medical Division of Houston, TX (Mishky, 2004). After the experience with the Fleet Manager and other patients who were bleeding uncontrollably, department personnel decided to examine hemostatic adjuncts to determine if change was needed. The CJCFPD EMS Committee meets monthly to perform quality improvement functions, review new products, and discuss EMS issues. Furthermore, the author shared material from military meetings that addressed changes and advances in hemostatic agents, providing discussion on improvements for CJCFPD. QuikClot® was deemed as a potential means of improving and upgrading the treatment regimen for trauma patients because of its availability, ease of use, and cost. The HemCon® dressing and Novo Seven were not available, were cost prohibitive, and not as easy to use. Other agents were not considered due to their lack of efficacy for field use and their availability. For the scope of this paper, the research is focused on these three adjuncts.

The impact on those served by the CJCFPD EMS system is immeasurable at the time this paper was written. As critical trauma patients are encountered and patients with uncontrollable bleeding are encountered, determinations may be made with the use of hemostatic adjuncts. Measurable results are obvious in the military community and there



is no reason the same results should not be realized in the civilian sector (Gullong, 2002, Demetriades, et al., 2004, Wilks, 2004, & Little, 2005).

The literature review had no significant impact on the research other than the fact that one might not expect a vast amount of material in the area of hemostatic agents. The literature review was enhanced by the author's accessibility to military publications and the author's deployment overseas. The professional association with Dr. Carr and the U.S. Special Operations Command (USSOCOM) Surgeon, Dr. Frank Butler, was invaluable in conducting the research on hemostatic agents. Dr. Butler was in Mogadishu, Somalia and Dr. Carr is a subject matter expert in hematology. Another valuable source of information was the Operational Trauma Symposium in Rota, Spain. Surgeons from Iraq, Afghanistan, and the Balkans were flown into Rota for a three-day conference on "lessons learned in combat medicine," then all returned to their respective theaters of operation. Hemostatic agents were a topic of significant discussion at that meeting and the author was a participant.

### Procedures

The research method used for this applied research project is descriptive. The participant conducted a literature search, examined multiple patient case studies, examined potential and existing test sites for new methods and materials, examined alternatives and adjuncts to hemorrhage control, and cites current studies that are being conducted. Current methods in the testing and use process are cited retrospectively and concurrently to illustrate compliance, reporting, and results issues. Interviews were

conducted with scientists and product developers to describe the use and impact of their products, citing specific examples of areas of use and test results.

The literature search resulted in over 50 internet articles and scientific sites. Interviews were conducted at the Special Operations Medical Conferences in 1999, 2000, and 2002-2005 annually. Dr. (Captain) Frank Butler, U.S. Navy and USSOCOM Command Surgeon was interviewed multiple years on specific uses of hemostatic agents, fielding of the adjuncts, and ongoing tests on different products. Dr. (Colonel) John Holcomb, U.S. Army, was interviewed at the 2004 conference and during the author's deployment about the particular nuances of different hemostatic agents. He was chosen as a subject matter expert and Trauma Director at the Uniformed Services University of the Health Sciences (USUHS) and Walter Reed Army Medical Center. Dr. (Colonel) Todd Fredricks was interviewed multiple times in 2004 and 2005 as a Board Certified Emergency Medicine physician and Flight Surgeon for Task Force Med Falcon, the authors deployed unit. Dr. (Colonel) Marcus Carr was interviewed as one of the principle developers of Novo Seven, Deputy Chief of Clinical Services, Task Force Med Falcon in 2004. Dr. Stanley Minken, Professor of Surgery, USUHS, and veteran surgeon of the Vietnam War, was interviewed at the Rota, Spain Operational Trauma Symposium in 2004, as were Dr. (Captain) John Perciballi, physician on the Forward Resuscitative Surgical System 4 (FRSS-4) in Operation Iraqi Freedom as professionals who have used or seen the effects of hemostatic adjunct use. Dr. (Captain) Gerald Wilks and Dr. (Commander) Peter Mishky, U.S. Navy, were also interviewed at Rota as both served as surgeons in multiple theaters in 2003 and 2004. More physicians and more healthcare providers were interviewed at Rota but for the sake of brevity and scope, their names are

referenced. (Spain, 2004). Interviews were conducted with Bart Gullong, Vice-President of Z-Medica, maker of QuikClot® in 2002 and 2003 at the Special Operations Medical Conference in Tampa, Florida. An interview was conducted with Mike Zoormajian, Product Manager for HemCon, Inc. in 2005 at the Special Operations Medical Conference in Tampa, Florida. Interviews were conducted with multiple field providers to include Lieutenant Mark Donald, Physicians Assistant, U.S. Naval Special Warfare Group, Virginia Beach, Virginia, who provided a classified brief on specific operations in December 2005 and Dr. (Major) Lisa DeWitt, Battalion Surgeon, 20<sup>th</sup> Special Forces Group (Airborne) in Tampa.

Each December since 1997, the author has attended the Special Operations Medical Association Conference (SOMA) and participated in focus groups, clinical tests, panel discussions, and conference presentations. Since the U.S. Food and Drug Administration (FDA) approved QuikClot® in 2002 and HemCon® in 2003, the testing and discussion have become more open and more widespread than prior to the approvals. In other words, many testing processes are kept quiet and not discussed in open forums prior to FDA approval, so material was somewhat limited prior to that time outside of USSOCOM.

Case studies included those contained in cited articles, the majority from military sources listed in the Resources section. Case studies were somewhat limited outside of the laboratory environment due to the infancy of the hemostatic agents examined and their limited use in the military and relative non-use in the civilian sector.

The author visited neighboring Fire Departments and EMS providers but found limited use of hemostatic agents. The Lee's Summit Fire Department tried

TraumaDex®, a starchy powder that reportedly promotes clotting in external bleeding. Due to the consistency of the powder and reviews on the product, this agent was not considered as a viable choice for this study (Alam, et al., 2004). It is not a consideration in the military medical system. No other agents were found in use in the region.

Personal observation was limited to the clinical environment and that was extremely limited. Almost all observation was conducted in the U.S. Army Hospital, Camp Bondsteel, Kosovo in 2004 and 2005. Observation was conducted on a limited basis in the field at CJCFPD in 2005.

Information was obtained by interview and observation from the sources listed previously in this section to conduct descriptive research in answering the questions in the applied research project. As with any research project, certain limitations existed.

Interviews and personal communications cited are bound by the knowledge and experience of the person providing the information. Opinions and anecdotal remarks are also factors and the data or useable information must be extracted by the researcher, the author in this case. The information provided is open to interpretation and the facts must be extracted to present as useful research material.

Limitations in research conducted on the internet may parallel those of personal communications and interviews as well. Internet articles, discussion groups, and focus areas routinely lack resources or citations to substantiate the material presented on a website. This limits the researcher's ability to validate information and confirm facts.

Incident reports filed by individuals involved in actual events were limited by perception, writing and grammar skills, and the time they were written versus the time of the incident. If a report is written two weeks after an incident as opposed to two hours

after an incident, the events described may not mirror the occurrence as they would if the report was written sooner after the incident. If the individual filing the incident report writes in a subjective manner as opposed to an objective manner, the researcher must find the facts in the subjective material.

Trade journals and professional publications were extremely useful but limited by the authors' opinions of medicine, medical adjuncts, expectations, experience, and personal accounts. Much like history books, multiple authors may interpret similar events in a dissimilar manner.

Lastly, limitations exist in the amount of published research material pertaining to hemostatic agents and adjuncts. The author searched public and university libraries with minimal success in his search for applicable research material. Legal libraries may contain isolated cases of physicians and hospitals and their legal issues with surgical cases and litigation; however, the author was unable to locate any specific examples of gross negligence concerning hemostatic agents.

## Results

Specific answers to the original research questions follow:

1. What methods are currently used by CJCFPD personnel to control massive hemorrhage secondary to trauma?

CJCFPD personnel currently use methods taught in accordance with the Paramedic National Curriculum and consistent with the guidelines listed in the PreHospital Trauma Life Support manual (Frame, 2003). Refresher training is conducted

for all CJCFPD personnel with material from the Brady Paramedic series (Bledsoe, et al., 2001). These materials stress direct pressure, bandaging, and elevation of the wound. These methods and materials help provide a framework for the CJCFPD Medical and Trauma Protocols that are used in the provision of EMS throughout the service area (Block, et al., 2004).

2. Why are other methods of hemorrhage control needed to reduce patient risk?

Other methods of hemorrhage control are needed to reduce patient risk in the CJCFPD service area to reduce the incidence of trauma death and increase trauma patient survivability. As noted previously, the leading cause of trauma death is uncontrolled bleeding (American Trauma Society, 2005). Even though current methods work in most cases, a hemostatic adjunct is needed in a small number of cases when conventional means are not effective (King, 2005).

3. What methods outside of CJCFPD exist for control of massive hemorrhage?

Outside of CJCFPD a multitude of methods exist for control of massive hemorrhage. Topical agents, zeolite, zeolite sponges, gels, gel-soaked sponges, chitosan dressings, tourniquets of various types, pastes, powders, Novo Seven, injectibles, recombinant factors, and other materials are part of the hemostatic agent and adjunct repertoire (Wu, 1997). QuikClot®, the HemCon® dressing, and various tourniquets are used by the U.S. Military in combat zones and have achieved some significant results (Eisman, 2004). The Novo Seven has been tested by the Australian Army and the Israeli Army but has not been used in a field setting in the U.S. Military yet (Carr, personal communication, 2004). Due to its cost, it is not considered a viable option for EMS until it becomes more economical (Carr, personal communication, 2004).

4. What are the obstacles to obtaining and using methods of hemorrhage control not currently available to CJCFPD personnel?

The first obstacle to any change in protocol is change itself. CJCFPD personnel have been using the same basic methods to stop bleeding since they were trained to work on an ambulance or held a license. Any method not currently available to personnel would meet some sort of resistance when making a change. The second obstacle to changing the protocol is getting the physicians who oversee the EMS program to change, especially if the adjunct in question has not been seen, used, or accepted by the oversight physicians. Another is cost. If the change generates a significant expense, the expense must be budgeted and approved by a board of directors (Westermann, 1999). Not all of the adjuncts and agents are available in the civilian market. Obtaining some of the adjuncts could not only be difficult - - it could be illegal.

5. What is the impact to the community of reducing the risk of uncontrollable hemorrhage?

The impact to the community of reducing the risk of uncontrollable hemorrhage was not measurable at the time this paper was written. Any time the risk of death is reduced in any community, an impact is made. A husband, a father, and a productive member of the community suffered a massive hemorrhage secondary to a cardiac diagnostic test in 2005 after QuikClot® was placed on ambulance on a trial basis in the CJCFPD service area. One of the Paramedics on scene, realizing that the patient was going into shock and unable to stop the blood loss with conventional means, poured a pouch of QuikClot® onto the arterial catheter insertion site. The bleeding stopped

immediately and the patient improved steadily until released from the hospital (King, 2005).

Interviews were conducted across the country and overseas during the author's deployment. Interviews with Bart Gullong and Jessica Perkins (personal communication, December, 2002 and December, 2004) of Z-Medica provided insight and hard data on QuikClot®. Case studies involving soldiers and limited cases of civilian use clearly showed the efficacy of the material in an objective manner. Photographs and scientific journals provided also showed objective data to dispel any myths about tissue burning secondary to the exothermic reaction reportedly produced with the use of QuikClot® (Alam, et al., 2004). Interviews with Captain Frank Butler, M.D., United States Navy (personal communication, December, 1999) clearly showed the need for hemostatic agents in the combat zone down to the lowest level, citing his experience in Mogadishu, Somalia in 1993. Colonel Marcus Carr demonstrated increasing successes in his interviews with the Recombinant Factor VIIa Novo Seven (personal communication, November, 2004) and its use by the Israeli Army and Australian Defense Forces. Colonel Todd Fredricks provided a first hand account of his medic's use of QuikClot® to save the life of a soldier in 2003 in Iraq during his interviews at Camp Bondsteel (personal communication, 2004). Specific research by Colonel John Holcomb on the Chitosan dressing and its use in uncontrollable hemorrhage was noted in his interview in Tampa, Florida (personal communication, December, 2004).

Alam, et al., conducted a study in 2003 and published it in May 2004 in the *Journal of Trauma, Injury, Infection, and Critical Care*. This article used swine models that suffered a 100% mortality rate if untreated. Treatment with conventional means of



hemorrhage control resulted in a 57% mortality rate, while treatment with adjuncts such as bovine clotting factors and chitosan dressings ranged from 26.6% to 75% mortality. The only agent resulting in a 0% mortality was QuikClot®. Two studies involved the comparison of the Advance Clotting Sponge®, or QuikClot® in a bag, and the material in granular form (Arnaud, et al., 2004). These studies showed that the clotting times were almost immediate and identical but the irrigation of the wound was much easier when using the sponges as opposed to the granular form (Arnaud, et al., 2004).

At the Special Operations Medical Conference in Tampa, Florida in 2003, special operation medics were observed applying QuikClot® to a simulated wound and the HemCon® to another wound (personal observation, 2003). The average time of application for QuikClot® was less than five seconds as it was opened and poured from a pouch, directly on the wound. The application of the HemCon® dressing ranged from 38 seconds to greater than 60 seconds. It presented with sticky surfaces and was difficult to apply without the sponge adhering to the gloved or bare hand of the medic.

Observing the tissue of soldiers in direct contact with QuikClot® granules as a result of wound treatment showed no signs of burning or tissue death due to burns (personal observations, 2004). Soldiers treated with the HemCon® sponge were not observed because the sponge was not available in the area of operation occupied by the author.

## Discussion

The findings in this descriptive research are supported in articles from scientific journals, newspapers, websites, interviews, actual case studies, abstracts presented at

conferences, and personal observations. Study results were comparatively similar to those included in the literature review and in findings throughout the study. One result that kept coming to the forefront was that of politics in the development and fielding of hemostatic agents. “But civilian researchers in the burgeoning field of hemorrhage control also say that it has become so politically charged, so clouded by institutional pride, that several have stopped cooperating with the military’s research laboratories, saying the labs often skew toward the products their respective branches endorse.” (Little, 2005). Members of the Army Institute of Medical Research repeatedly make the claim that QuikClot® granules cause severe tissue burning and trauma secondary to the exothermic reaction produced during its use (Holcomb, et al., 2004). However, personal observations by the author in the emergency room and operating rooms during a combat deployment revealed nothing of the sort. Studies by Alam & Rhee, et al. showed a distinct lack of burning and tissue damage after QuikClot® use directly on lacerated organs such as the liver and lungs.

The research question concerning hemostatic adjuncts and their impact on the citizens of the CJCFPD service area is not answered yet. Although there is a documented use case study, how is the impact measured? How is the impact of salvaging an individual life measured? Is it measured by the income an individual makes due to a reduced risk? Is it measured in the music a composer writes who would have died from an otherwise uncontrollable hemorrhage? How does one put a price on a citizen who is saved from certain death by the use of a risk reducing agent? The case of the bleeding catheterization site made an impact on the patient’s family, the employer, and other members of the community who come in contact with the patient. One could also deduct

that an impact resulted on the healthcare institution that performed the initial cardiac test, the physician and technicians who conducted that test, the medical personnel at the second receiving hospital who saw the QuikClot® work for the first time, the ambulance crew who used the adjunct, and those who heard the story about this event (P. Lininger, personal communication., 2004).

The hemostatic agents examined appear to work in some fashion, some much more effectively than others (Alam, et al., 2004). However, Dr. Perciballi (2004) stressed that each agent has its specific use. The HemCon® sponge is most effective when the medic can observe the vessel that is bleeding and place the bandage directly on the hole in the vessel, holding it in place for three minutes or more (Perciballi, 2004). If you can't see the hole directly, then QuikClot® appears to work more effectively (Perciballi, 2004). Perciballi stated that "each has its own place and specific use by the combat medic." He likened it to using the right tool for a specific job.

The obvious benefit to the citizens in the CJCFPD service area is that hemostatic agents are available to provide a new and more effective means of treating uncontrollable hemorrhage. The results of this study show that different adjuncts provide varying degrees of clotting assistance with a differing degree of efficacy over a wide price range.

The cost of hemostatic agents in the civilian sector ranges from \$20 per dose up to in excess of \$3,000 per treatment (U.S. Cavalry, 2005 & M. Carr, personal communication, 2004). This is a significant issue with any prudent EMS provider. Fielding and availability are other issues as some of the adjuncts examined are not yet available in the civilian market, such as the HemCon® dressing. If the items are on the

market, many services cannot afford them, cannot afford the training costs to put them in the field, or do not know where to get them.

The author's interpretation of the results is that QuikClot® works best and is most economical and easiest to use. It costs roughly \$20 per dose from multiple distributors and is the only hemostatic agent that exhibited a 0% mortality rate in controlled testing (Alam, et al., 2004).

Implications for the CJCFPD include the benefit of providing a greater level of care to the constituents of the District. Advances in trauma care occur frequently and this advanced treatment helps stop uncontrollable hemorrhage and save lives. It provides an improvement in the EMS system and level of care offered. The training provided with the implementation of hemostatic agent use allows the personnel at CJCFPD to acquire new knowledge and thereby educate the public in the benefits of improved levels of care. It allows the citizens and employees to be more aware of the improvement process at CJCFPD and exhibits a commitment to quality. This has the potential to benefit CJCFPD in many ways to include healthier patients, better trauma care, preservation of life, and an improved public image.

### Recommendations

The Central Jackson County Fire Protection District should fully field QuikClot® on its ambulances, engines, and in all EMS sets. It should also conduct further initial training and education to include research methodology and case studies. Quality improvement personnel should review each use of the hemostatic adjunct and the system

Medical Director should review each use with medics in a regularly conducted morbidity and mortality conference.

The short term goals for the District include initial training on QuikClot®, evaluation of each use through the quality improvement process, continuing training and evaluation of hemostatic agent use, and a cyclic review of the hemostatic agent and its use. Continued attendance at conferences and venues where hemostatic agents are reviewed and regular meetings with the system Medical Director is involved in discussion and review of medical practices is also recommended.

Expected benefits to the District include a higher level of patient care for constituents and a decrease in mortality attributed to uncontrollable hemorrhage, both secondary to trauma and other mechanisms. Ongoing research is needed to dispel myths association with various adjuncts (Holcomb, et al., 2004) and as a means to continually improve quality of patient care. Additional research results in new products, increasing competition and decreasing prices. Before Novo Seven is fielded by EMS agencies, it will have to come down in price. Flight programs that are able to trade out with receiving hospitals are the only EMS systems that will carry Novo Seven until the cost is more reasonable, the reason being that hospitals are more effective at recovering the costs of medications than EMS agencies are.

Retrospective studies are needed with hemostatic agents to determine their efficacy, their uses, and to determine which adjunct is best for which circumstance. The products are new enough that there is not a lot of documented use and no retrospective studies to speak of with statistically significant numbers. The majority of the data

published on hemostatic agents are laboratory data instead of actual patient use. Further evaluation in this area is most needed.

Researchers who may wish to replicate this study need access to manufacturers and their spokespersons, products that are not in the civilian market, access to labs that do medical testing procedures, live animal labs, and teaching hospitals with trauma programs. Furthermore, access to military personnel who frequently test new advances in medicine and trauma care is extremely helpful. A population that suffers a high incidence of traumatic injuries is useful, such as the military in a time of war or a violent urban area, although somewhat disheartening and disturbing. Most of all, the ability to look at medical products in an unbiased manner from a patient's point of view is important.

To leave things "as is" in medicine is not a "best practices" approach for one to take. Medical advances are dynamic and occur on a daily basis. In medicine, doing what is best for the patient involves continuous quality improvement. That is the goal in this study of hemostatic agents in reducing the impact of uncontrollable bleeding secondary to traumatic injury in the Central Jackson County Fire Protection District.

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